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Guidance for the Reregistration of Pesticide Products Containing Propazine as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

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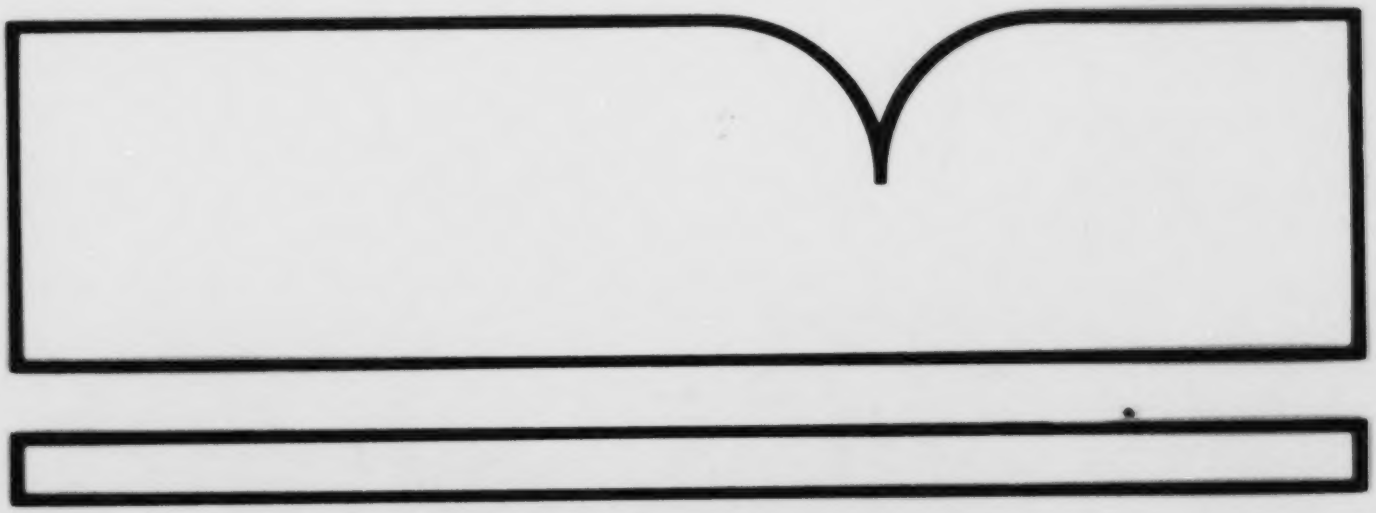

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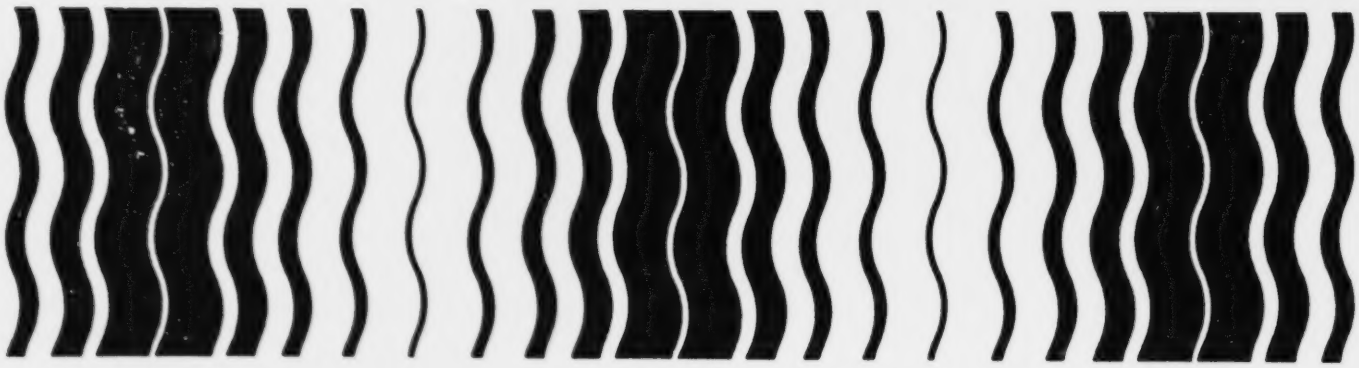
540/RS-89-022

EPA

Guidance for the Reregistration of Pesticide Products Containing PROPAZINE as the Active Ingredient



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This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of date requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

PROPAZINE

OPP Chemical Code 080808

AS THE ACTIVE INGREDIENT

CASE NUMBER 0230

CHEMICAL ABSTRACTS SERVICE NUMBER: 139-40-2

DECEMBER 1988

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	Active ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
LC50	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD50	Median lethal dose - a statistically derived single dose than can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
MP	Manufacturing Use Product

NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts per million
TMRC	Theoretical Maximal Residue Contribution

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request,[1] focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1]The scientific reviews and Compendium of Acceptable Uses may be obtained from the OPP Public Docket. Write to OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, D.C. 20460

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submittal of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any

time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submittal of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICAL COVERED BY THIS STANDARD

A. DESCRIPTION OF CHEMICAL

Common Name: Propazine

Chemical Name: 2-chloro-4,6-bis(isopropylamino)-s-triazine

Chemical Abstracts Service (CAS) Number: 139-40-2

OPP Chemical Number: 080808

Molecular Weight: 229.7

Empirical Formula: $C_9H_{16}N_5Cl$

Trade Name(s): Milogard®, Gesamil®, Milo-Pro, Pramitol, Prozinex

Physical State: Crystalline solid

Color: Colorless

Odor: Odorless

Melting Point: 212 to 214°C

B. USE PROFILE

Type of Pesticide: Herbicide

Pests Controlled: Grassy and broadleaf weeds

Registered Uses: Terrestrial food crops and nonfood crop areas

Predominant Use: >99 percent is used on sorghum

Mode of Activity: Inhibition of cell division and photosynthesis

Formulation Types: Wettable powders (90 to 26.6 percent active ingredient); flowable concentrates (44.5 to 18.7 percent active ingredient); soluble concentrate liquid (43 percent active ingredient)

Method of Application: Preplant or preemergent, as a spray by ground or aerial equipment

Application Rates: 1 to 2 pounds active ingredient per acre; however, as much as 3.2 pounds active ingredient per acre may be used on certain fine textured or highly organic soils for sorghum and from 1.6 to 13.3 pounds per acre for nonfood crop areas

C. BACKGROUND

Three Data Call-In (DCI) Notices have been issued for propazine. The first, in August 1983, required chronic toxicity data. Studies submitted in response to this DCI have been reviewed and are discussed in this document. Many of the submitted studies were unacceptable and additional chronic data continue to be required.

In July 1984, the Agency issued a DCI Notice for groundwater data for propazine. This Notice was issued for chemicals which may have the potential to contaminate groundwater based on such factors as the chemical's structure, solubility and use patterns.

Based on the Agency's review of the data submitted in response to the July 1984 DCI, it was determined that propazine and/or its degradate(s) do have the potential to leach into groundwater. However, the Agency decided that additional data were needed to define further the extent of the groundwater problem, and, in April 1988, issued the third DCI Notice. This Notice required a small-scale retrospective groundwater monitoring study on propazine.

Based on its potential to contaminate groundwater, propazine has been included in EPA's National Pesticide Survey.

In response to the 1988 DCI Notice, the manufacturer of propazine, Ciba-Geigy, elected to cancel its registrations of propazine. To date, no other registrant has committed to generate data required by that Notice. All products have either been cancelled or suspended.

III. AGENCY ASSESSMENT

A. SUMMARY

Based on a review of the available data on propazine, the Agency has reached the following conclusions regarding this chemical. These data are discussed in more detail in the following sections.

1. Propazine has low acute toxicity. It is not teratogenic in the rat. It is, however, oncogenic and the Agency has classified propazine as a Group C oncogen (potential human carcinogen) based on positive findings in the rat.

2. Propazine has been designated as a chemical with a high potential for leaching into groundwater and is included in the EPA National Pesticide Survey.

3. The Agency will not, at this time, formulate specific regulatory positions regarding propazine unless a registrant commits to generate data in support of this chemical.

B. TOXICOLOGICAL ASSESSMENT

The Agency has reviewed the available acceptable toxicological data for propazine. The results of that review are set forth below:

ACUTE TOXICITY. Propazine has low acute oral toxicity, with an LD_{50} for rats of >5 g/kg (Toxicity Category IV). It has moderate acute dermal and inhalation toxicity, with an acute dermal LD_{50} of of >2 g/kg for rabbits (Toxicity Category III) and an acute inhalation LC_{50} of >2.1 mg/L/4 hour for rats (Toxicity Category III).

Propazine is moderately irritating to rabbit eyes. No corneal opacity was observed but some conjunctival irritation was observed at 24 hours with clearing by day 4 (Toxicity Category IV). It is moderately irritating to rabbit skin demonstrating a Primary Irritation Score of 3.9/8.0 with erythema, eschar, and edema. Improvement was noted by 72 hours. (Toxicity Category III)

SUBCHRONIC TOXICITY. No acceptable subchronic studies are available. However, because an acceptable chronic rat study is available and a nonrodent chronic study is required, oral subchronic studies are not required.

Since the use of propazine would result in repeated human skin contact, but of a limited frequency and duration, a 21-day dermal toxicity study is required. Other subchronic studies are not required.

CHRONIC TOXICITY. Sufficient data are available to satisfy the data requirements for a chronic feeding study in a rodent species (rat). A chronic feeding study in nonrodents is required.

In the rat study, 60 male and 60 female CD rats/dosage level were given 0, 3 ppm (0.15 mg/kg/day), 100 ppm (5.0 mg/kg/day), and 1000 ppm (50 mg/kg/day) of propazine in their diets for 2 years. Generally, there were no treatment-related toxicity signs, or changes in hematology, clinical chemistry, or urinalysis. Body weights of both males and females of the high-dose groups were significantly decreased in comparison to controls, as well as mean food consumption. There was an increase in subcutaneous masses and nodules in females of the 1000 ppm dose group which correlated with the increased microscopic findings of mammary gland tumors (see below). The systemic NOEL was designated as 100 ppm based on the depression in body weights in the high-dose male and female groups.

ONCOGENICITY. There are sufficient data available to satisfy the data requirements for oncogenicity studies.

In the rat study (discussed above), gross necropsy showed an increase in subcutaneous masses and nodules in females of the 1000 ppm dose group, which correlated with an increase in mammary neoplasms. These neoplasms included benign tumors (adenomas, fibroadenomas) and malignant tumors (adenocarcinomas, papillary carcinomas).

In a mouse study, 60 male and 60 female CD-1 mice/dosage levels were given 0, 3 ppm (0.45 mg/kg/day), 1000 ppm (150 mg/kg/day, and 3000 ppm (450 mg/kg/day) of propazine in their diets for 2 years. Propazine was not found to be oncogenic in this study. There were increased incidences of non-neoplastic lesions in high-dose males of hemosiderin-laden macrophages and in high dose females of myocardial degeneration. The systemic NOEL was 1,000 ppm.

In accordance with the Agency's Guidelines for Assessing Carcinogenic Risk, EPA has classified propazine as a Group C compound (potential human carcinogen). This classification is based on the following:

In the rat study, female rats developed benign and malignant mammary tumors. A statistically significant dose-related trend

was found for malignant and benign tumors, combined, and a statistically significant pairwise comparison was found for high dose vs. control for malignant and benign, combined. Although these tumors were significant only at the high dose, at which the maximum tolerated dose was apparently achieved or slightly exceeded, the Agency believes that they were, nevertheless, convincing since the increase in these tumors in females at the high dose exceeded that of historical controls.

Structure activity on related triazines provides support for the association of mammary tumors with this class of chemicals. Propazine is structurally related to simazine, cyanazine, atrazine and terbutryn. Atrazine and terbutryn have both been classified as Group C oncogens (mammary tumors in rats).

Propazine induced a dose-related, positive response (without metabolic activation) in Chinese hamster cells (and a weak non-dose-related one with activation). Propazine was negative in a nucleus anomaly assay and in a DNA damage/repair assaay in rat hepatocytes.

Propazine was negative for oncogenicity in mice. For malignant lymphomas in females, multiplicity of tumors per animal (tumor load) was enhanced relative to dose. This suggests that increased or enhanced metastatis factors may be operating in the mouse.

Although the Agency determined that a Group C classification is appropriate for propazine, EPA has concluded that quantitative risk assessment is not warranted. This conclusion is based on the fact that the tumors observed in the rat study occurred in only one sex, were mostly benign, and were significantly increased only at the highest dose.

TERATOGENICITY. There is an acceptable teratogenicity study in the rat. A developmental toxicity study in a second species (rabbit) is required.

In the rat study, propazine was administered to groups of 25 female Sprague-Dawley rats at dosage levels of 0, 10, 100 and 500 mg/kg/day. It was not teratogenic at dosages up to 500 mg/kg/day, the highest dose tested (HDT). Maternal toxicity was observed in the mid- and high-dose females as decreased food consumption and decreased body weight gain. Additionally, high-dose females exhibited periods of salivation (clear) during gavage. The NOEL for maternal toxicity was 10 mg/kg/day.

Developmental toxicity was observed at the high dose as increased 14th ribs, incomplete ossification of skeletal structures and decreased fetal body weight. At the mid-dose, delayed ossification of the interparietals was observed. The NOEL for developmental toxicity was 10 mg/kg/day.

REPRODUCTION. There are sufficient data available to satisfy the requirements for a reproductive toxicity study for propazine.

In a three-generation, 2-litter per generation, study, male and female CD rats were continuously given propazine in their diets at dosage levels of 0, 3 ppm (0.15 mg/kg/day), 100 ppm (5 mg/kg/day), and 1000 ppm (50 mg/kg/day). No compound-related effects for clinical signs or mortality were observed during the study.

At the 1000 ppm dosage level, a depression in body weight was observed in both male and female parental animals. Food consumption was reduced at the high dose in the F_0 and F_2 females and at all dosage levels of the F_1 and F_2 male groups. No compound-related effects in male or female fertility, gestation length, pup viability, and pup survival were observed. Mean body weights of male and female pups at day 21 of lactation were significantly reduced at 1000 ppm in the F_{1b}, F_{2a}, F_{2b}, F_{3a}, and F_{3b} litters. Altered absolute or relative organ weights were observed in all parental groups at the high dose level. F_0 males showed an increased relative testicular and relative heart weight, F_1 males displayed an increased relative liver and heart weight, and F_2 males and females had decreased absolute liver weights while the F_2 males had decreased relative liver weight, relative testicular weight, and kidney weight. No histological findings attributable to propazine were observed in parental or weanling animals. The reproductive NOEL is 100 ppm, based on the depression in pup weights at 21 days postpartum in the F_{1b}, F_{2a}, F_{2b}, F_{3a}, and F_{3b} litters.

MUTAGENICITY. There are sufficient data available to satisfy the mutagenicity data requirements.

In a gene mutation assay, propazine was tested in V79 Chinese hamster cells with and without microsomal activation. It produced a dose-related positive mutagenic response without metabolic activation and a weak (non-dose-related) positive response with metabolic activation.

In a structural chromosomal aberration assay, propazine was administered in the diet to groups of six male and six female Chinese hamsters. The cells displaying anomalies on nuclei in treated cells did not differ significantly from the negative controls. Propazine was not considered mutagenic in this assay.

DNA damage/repair assays were performed on rat hepatocytes with propazine. The mean number of silver grains per nucleus in the vehicle control and treated cells was not markedly different. Propazine was not mutagenic under the conditions of this assay.

METABOLISM. There are no acceptable metabolism studies; a general metabolism study is required.

C. OTHER SCIENCE FINDINGS

ECOLOGICAL EFFECTS. The Agency has limited ecological effects data.

Based on an acceptable fish acute toxicity study on technical propazine, with an LC_{50} of 16.5 ppm for Rainbow trout, propazine can be characterized as slightly toxic to coldwater fish.

In the partially acceptable avian dietary study with a formulated product, an LC_{50} of 32000 ppm was reported for Mallards, which indicates that the compound is practically nontoxic for waterfowl. There are, however, currently no requirements for studies on formulated products.

There are sufficient data to characterize propazine as relatively nontoxic to honey bees when bees are exposed to a direct treatment.

Based on use patterns, estimated concentrations and the available toxicity data, EPA has determined that the use of propazine will not pose a hazard to endangered wildlife (fish and avian) or plants.

ENVIRONMENTAL FATE. Available data are insufficient to fully assess the environmental fate of propazine.

In an acceptable aerobic soil study, propazine degraded with a half-life of 12-24 weeks in nonsterile loamy sand soil incubated in the dark at 25°C. In sterile loamy sand soil, propazine degraded with a half-life of 8-12 weeks in the dark at 25°C.

In an acceptable anaerobic soil study, propazine degraded with a half-life of 8 weeks in nonsterile loamy sand soil incubated anaerobically in the dark at 25°C following 4 weeks of aerobic incubation.

In an acceptable leaching and absorption/desorption study, propazine was mobile in sandy loam, loam, and clay loam soils, and was very mobile in loamy sand soil.

The following information is based on studies which, while not acceptable for fulfilling data requirements, do provide supplemental information on propazine:

Propazine was stable to hydrolysis during 28 days of incubation at 30°C in aqueous solutions buffered at pH 7 and 9. In the pH 5 buffered solution, the half-life was >28 days. It was relatively stable to photolysis in aqueous solutions irradiated with natural sunlight.

Propazine was very mobile in loamy sand and loam soils; mobile in sandy loam, silt soils, and sand soil; and slightly mobile in loam soil.

Propazine dissipated with a half-life of <30-149 days and <31 days in sandy loam soil in tests conducted in two different locations. It dissipated with a half-life of 60->357 days in silt loam soil.

Groundwater. Based on the available data, propazine is persistent, moderately mobile and stable to hydrolysis, photolysis and microbial degradation, demonstrating a potential to contaminate groundwater. Propazine has been detected in groundwater samples in a total of 8 states. The maximum concentrations found were 20 ppb in surface water and 300 ppb in groundwater.

Reentry. Based on the low acute toxicity of propazine and its use patterns, the Agency finds that reentry data are not required.

Spray Drift. No data are available to evaluate the spray drift potential of propazine and data are required.

PRODUCT CHEMISTRY. EPA has evaluated the available data which identify the ingredients, materials and manufacturing process and provide information on the physical and chemical properties of propazine. Since propazine is a secondary amine, there is a concern regarding potential for nitrosoamine contamination. However, currently available data are insufficient to thoroughly evaluate this potential contamination.

D. TOLERANCE REASSESSMENT

Tolerances have been established for negligible residues of propazine in or on sweet sorghum and its fodder, forage and grain at 0.25 ppm (40 CFR 180.243).

EPA has evaluated the residue data supporting these tolerances. The results of this evaluation follow.

Residue Data. The nature of the residues in both plants and animals are not adequately understood. Additional data are required. Data on storage stability are unavailable. Adequate analytical methods are available for data collection pertaining to residues of propazine. Additional methods may be required if metabolism studies indicate that additional metabolites constitute residues of toxicological concern in plants or animals.

Sufficient data are available to ascertain the adequacy of the established tolerances for residues of propazine in or on sorghum fodder, sorghum forage, sorghum grain, and sweet sorghum. However, processing studies are required for grain sorghum and sweet sorghum.

There are no Canadian, Mexican or Codex MRL tolerances for sorghum; therefore, no compatibility questions exist.

Toxicology Data. The Provisional Acceptable Daily Intake (PADI) for this chemical is 0.02 mg/kg/day, based on the 2-year rat feeding/oncogenicity study. The systemic NOEL was set at 100 ppm (5 mg/kg). The safety factor used was 300 based on an uncertainty factor of 100 to account for inter- and intra-species differences with an additional factor of 3 to account for the incompleteness of the chronic data base since the one-year dog feeding study may yield a more sensitive toxicological endpoint.

The Theoretical Maximum Residue Contribution (TMRC) for the U.S. population average is 0.0003 mg/kg/day, equivalent to 1.7 percent of the PADI. The TMRC is based on published as well as pending tolerances.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITION AND RATIONALE

Position. The Agency has determined that it is not necessary, at this time, to formulate specific regulatory positions regarding propazine. Should it become necessary to establish individual positions, based on review and evaluation of the available data and other relevant information, the Agency would consider regulatory positions regarding such areas as special review, tolerances and groundwater.

EPA will, however, remove the reference to the designation "negligible residue," a term which is now considered obsolete, from the tolerance expression in 40 CFR 180.243 at such time as the regulation may be amended in the future or as soon as practicable. In the event that all registrations for food uses of this pesticide are cancelled prior to the amendment of the tolerance regulation, the tolerances will be scheduled for revocation and the need to amend the regulation will have become moot.

Rationale: In April 1988, the Agency issued a DCI Notice to the registrants of propazine products requiring a small-scale retrospective groundwater monitoring study. In response to that Notice, the manufacturer of propazine elected to cancel its registrations of propazine. No other registrant has committed to generate the required data, and, therefore, all products have been cancelled or suspended. Since suspended products cannot be marketed, there is no reason to impose new label requirements which apply only to products introduced into the marketplace after issuance of a Standard.

If a registrant commits to generate these data and complies with the requirements of FIFRA, as set forth in this document, the Agency will formulate specific regulatory positions regarding this chemical. However, EPA believes revision to the tolerance expression, if the suspended registrations are not cancelled, is appropriate to eliminate obsolete terminology.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain this pesticide, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this document.

C. ACCEPTABLE RANGES AND LIMITS

Product Composition Standard. To be registered or reregistered under this Standard, manufacturing-use products (MP's) must contain this pesticide. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1 percent.

Acute Toxicity Limits. The Agency will consider registration of technical grade and MP's containing this pesticide provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

Use Patterns. To be registered under this Standard, MP's may be labeled for formulation into end-use products for acceptable use patterns. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in Table A for that use pattern.

D. LABELING

Should a registrant commit to generate data and maintain product registrations for propazine, labeling must be updated. Once a registrant has committed, the Agency will provide specific labeling statements unique to propazine. In addition, the following standard labeling requirements will apply.

All products must bear appropriate labeling as specified in 40 CFR 156.10, PR Notices 83-2, 83-3 and below. Appendix II contains information on label requirements.

The ingredient statement must list the active ingredient as:

Propazine (2-chloro-4,6-bis(isopropylamino)-s-triazine) . . . . . %

Time Frames for Compliance. Pesticide products containing propazine as an active ingredient may not be released for shipment by the registrant after December 1989, unless the product bears an amended label which complies with the requirements of FIFRA as set out in this Standard.

Pesticide products containing propazine as an active ingredient may not be distributed or sold by any person after December 1990, unless the product bears an amended label which complies with the requirements of this Standard.

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

   1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

   2. The data requirements listed in Tables A and B.[2]

   3. The labeling requirements specified for manufacturing use products in Section IV.

   4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

   1. The data requirements listed in Table A.

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[2]Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end-use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end-use products at this time. Therefore, most Registration Standards do not contain a Table C.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the generic data exemption,[3] the data requirements listed in Table C.

3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

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[3]If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end-use producers lose the exemption, and become subject to the data requirements in Table A.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4]Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person

who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

[Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec.

3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol

changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to

conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing

stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6. (cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Office of Pesticide Programs
OPP Mailroom (TS-767C)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Attn: Propazine Registration Standard

All submittals in response to this Registration Standard are non-fee items, including 90-day responses, protocols and waiver requests, data, and revised labeling. Submittals must be clearly identified as being in response to the Registration Standard. Under no circumstances may Registration Standard responses be combined with other types of filings for which fees are required.

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 9 months of receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPAZINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158 - Subpart C - 120 Product Chemistry						
Product Identity and Composition						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	No		Yes[1]	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	No		Yes[2]	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	TGAI	All	No		Yes[3]	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	No		Yes[4]	6 Months
63-3 - Physical State	TGAI	All	No		Yes[4]	6 Months
63-4 - Odor	TGAI	All	No		Yes[4]	6 Months
63-5 - Melting Point	TGAI	All	No		Yes[4,5]	6 Months
63-6 - Boiling Point	TGAI	All	No		Yes[4,6]	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPAZINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158 - Subpart C - Product Chemistry						
Physical and Chemical Characteristics (cont'd)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	No		Yes[4]	6 Months
63-8 - Solubility	TGAI or PAI	All	No		Yes[4]	6 Months
63-9 - Vapor Pressure	TGAI or PAI	All	No		Yes[4]	6 Months
63-10 - Dissociation Constant	TGAI or PAI	All	No		Yes[4]	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	All	No		Yes[4,7]	6 Months
63-12 - pH	TGAI	All	No		Yes[4,8]	6 Months
63-13 - Stability	TGAI	All	No		Yes[4]	6 Months
Other Requirements						
64- 1 - Submittal of Samples	N/A	All	N/A		No	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPAZINE

§158 - Subpart C - Product Chemistry

1/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

2/ A detailed discussion of all impurities that are or may be present at $\geq$ 0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted. This discussion must also address the possible formation of nitrosamines.

3/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used. All nitrosoamines must be identified and quantified in six samples of each product; two samples of each must be analyzed shortly after production, 3 months after production, and 6 months after production. A method sensitive to 1 ppm of N-nitroso contaminants must be used. An upper limit must be provided (and certified) for all nitrosoamines found. Certifications should be submitted on EPA Form 8570-4 (Rev. 2-85).

4/ Physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, K_{ow}, pH, and stability) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

5/ Data needed if the technical chemical is a solid at room temperature.

6/ Data needed if the technical chemical is a liquid at room temperature.

7/ Required if the technical chemical is organic and nonpolar.

8/ Required if the test substance is dispersible with water.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPAZINE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.240 Residue Chemistry					
171-4 - Nature of the Residue (Metabolism)					
- Plants	PAIRA	Partially	00024330, 00024436 00024728, 00087881 00111694	Yes[1/2/]	18 Months
- Livestock	PAIRA	Partially	00087890	Yes[2/3/]	18 Months
171-4 - Residue Analytical Methods	TGAI and Metabolites	Yes	00016404, 00023280 00038224, 00041371 00068044, 00080630 00087887, 00087889 00112982, 00118949 00119532, 00140830 40933501	Reserved[4/]	
171-4 - Storage Stability Data	PAI	No		Yes[5/6/]	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPAZINE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry					
171-4 - Magnitude of the Residue					
- Cereal Grains Group[7/]					
o Sorghum	TEP	Partially	00016607, 00016990, 00016991, 00016992, 00026271, 00044427, 00047878, 00063246, 00065582, 00068044, 00087880, 00087884, 00105170, 00111672, 00111693, 00118949	Yes[8/]	24 Months
- Forage, Fodder, and Straw of Cereal Grains Group[9/]					
o Sorghum forage, fodder, hay, and silage	TEP	Yes	00016607, 00016990, 00016992, 00026271, 00044427, 00047878, 00063246, 00065582, 00068044, 00087880, 00087884, 00105170, 00111672	No	
171-4 - Meat/Milk/Poultry/Eggs	TEP	Partially	00087885, 00093525, 00140830	Reserved[10/]	

1/ Data depicting the uptake, distribution, and metabolism of ring-labeled [^{14}C]propazine in sorghum following preplant application at a rate sufficiently high to permit complete ^{14}C-residue identification must be submitted.
2/ Representative samples from the above-described tests must also be analyzed using accepted enforcement methods to ascertain that these methods will determine all possible metabolites of concern.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPAZINE

3/ Metabolism studies utilizing ruminants and poultry must be submitted. Animals must be dosed for at least 3 days with ring-labeled [^{14}C]propazine at a concentration that will result in sufficient residues for characterization in the tissues, milk, and eggs. Studies must elucidate the identities and quantities of all metabolites in milk, eggs, liver, kidney, muscle, and fat. Milk and eggs must be collected twice daily during the dosing period. Animals must be sacrificed within 24 hours of the final dose.

4/ Additional methods, validation data, and residue data (for representative commodities) may be required if the metabolism studies requested in the sections entitled "Nature of the Residue in Plants" and "Nature of the Residue in Animals" reveal additional metabolites of toxicological concern in plants or animals.

5/ The storage intervals and conditions for all samples used to support all tolerances for residues of propazine in or on sorghum must be submitted. These data must be accompanied by data depicting the decline of residues during the interval and under the conditions specified. In laboratory tests using fortified samples, the pure active ingredient and pure metabolites (if necessary) must be used. However, if field-weathered samples are used, the test substance must be a typical end-use product.

6/ Residue data requested in this Standard must be accompanied by information describing the storage conditions and intervals for all samples analyzed. These data must be accompanied by fortification recovery data depicting the stability of residues of concern in appropriate sample substrates under the storage conditions and for the time intervals specified. In laboratory tests using fortified samples, the pure active ingredient and pure metabolites (if necessary) must be used. However, if field-weathered samples are used, the test substance must be a typical end-use product.

7/ If registrant seeks a crop group tolerance, use directions must be proposed and appropriate supporting data must be submitted for three additional representative commodities (corn, rice, and wheat)

8/ Data depicting propazine residues of concern in syrup processed from sweet sorghum and in milled products (flour and starch) and grain dust processed from grain sorghum bearing measurable, weathered residues must be submitted. If residues concentrate in any of these processed commodities, appropriate food/feed additive regulations must be proposed.

9/ If registrant seeks a crop group tolerance, use directions must be proposed and appropriate supporting residue data submitted for corn and wheat.

10/ Presently, the nature of the residue in animals is not adequately understood. On receipt of the data requested in the section entitled "Nature of the Residue in Animals," the appropriate nature of tolerances for residues in animal products will be determined and, with consideration for any newly found metabolites of toxicological concern, the adequacy of the available data regarding the magnitude of the residue in meat, milk, poultry, and eggs will be determined.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPAZINE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.290 Environmental Fate						
DEGRADATION STUDIES-LAB						
161-1 - Hydrolysis	TGAI or PAIRA	A,B	Partially	00153708	Yes[1/]	9 Months
Photodegradation						
161-2 - In Water	TGAI or PAIRA	A,B	No		Yes	9 Months
161-3 - On Soil	TGAI or PAIRA	A	No		Yes	9 Months
161-4 - In Air	TGAI or PAIRA	A	No		No[2/]	
METABOLISM STUDIES-LAB						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	Yes	00153712	No	
162-2 - Anaerobic Soil	TGAI or PAIRA	A	Yes	00153713	No	
162-3 - Anaerobic Aquatic	TGAI or PAIRA	N/A	No		No[3/]	
162-4 - Aerobic Aquatic	TGAI or PAIRA	N/A	No		No[3/]	
MOBILITY STUDIES						
163-1 - Leaching and Adsorption/ Desorption	TGAI or PAIRA	A,B	Partially	00152997	Yes	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPAZINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.290 Environmental Fate						
MOBILITY STUDIES (cont'd)						
163-2 - Volatility (Lab)	TEP	A	No		Yes	12 Months
163-3 - Volatility (Field)	TEP	A	No		Reserved[4/]	15 Months
DISSIPATION STUDIES-FIELD						
164-1 - Soil	TEP	A,B	No		Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	N/A	No		No[3/]	
164-3 - Forestry	TEP	N/A	No		No[3/]	
164-4 - Combination and Tank Mixes	TEP	A,B	No		No[5/]	
164-5 - Soil, Long-term	TEP	A	No		Yes[6/]	50 Months
ACCUMULATION STUDIES						
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No		Reserved[7/]	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPAZINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.290 Environmental Fate						
ACCUMULATION STUDIES (cont'd)						
165-3 - Irrigated Crops	TEP	N/A	No		No[3/]	
165-4 - In Fish	TGAI or PAIRA	A,B	No		Yes	12 Months
165-5 - In Aquatic Nontarget Organisms	TEP	N/A	No		Reserved[8/]	
§158.390 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B	No		No[9/]	
132-1 - Soil Dissipation	TEP	N/A	No		No[9/]	
133-3 - Dermal Exposure	TEP	A,B	No		No[9/]	
133-4 - Inhalation Exposure	TEP	A,B	No		No[9/]	
§158.440 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	A,B	No		Yes	12 Months
201-1 - Drift Field Evaluation	TEP	A,B	No		Yes	24 Months
§158.340 Human Exposure Data	TEP	A,B	No		Reserved[10/]	
SPECIAL TESTING						
Groundwater Monitoring Study	TEP	A,B	No		Yes[11/]	36 Months[12]

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPAZINE

§158.290 Environmental Fate, §158.390 Reentry Protection, §158.440 Spray Drift, and §158.340 Human Exposure Data

1/ The study fulfills data requirements for pH 7 and 9. Data are required for pH 5.
2/ Based on the use patterns, this study is not required.
3/ Data not required because there are no aquatic or aquatic impact uses.
4/ Pending the result of the laboratory volatility study (163-2).
5/ Currently not imposed for this product (single ingredient).
6/ Preliminary data suggest that the half-life of propazine > 12 months.
7/ Pending the results of the confined accumulation study.
8/ Pending the results of the laboratory fish accumulation study.
9/ Based on toxicity and use patterns, these data are not required.
10/ Pending the results of the toxicological studies.
11/ A small-scale retrospective groundwater monitoring study is required as detailed in the Agency's April 11, 1988, Data Call-In Notice.
12/ A protocol must be submitted within 120 days. The final study report must be submitted within 3 years of your receipt of notification of acceptance of the protocol. In the interim, semi-annual progress reports are due.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPAZINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.340 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral - Rat	90WDG	A,B	Yes	00111699	No	
81-2 - Acute Dermal	90WDG	A,B	Yes	00111700	No	
81-3 - Acute Inhalation - Rat	90WDG	A,B	Yes	00111701	No	
81-4 - Eye Irritation - Rabbit	90WDG	A,B	Yes	00111702	No	
81-5 - Dermal Irritation - Rabbit	90WDG	A,B	Yes	00111703	No	
81-6 - Dermal Sensitization - Guinea Pig	TGAI	A,B	No		Yes	9 Months
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	N/A	No		No[1/]	
SUBCHRONIC TESTING						
82-1 - 90-Day Feeding						
o Rodent	TGAI	A,B	No		No[2/]	
o Nonrodent	TGAI	A,B	No		No[2/]	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPAZINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additonal Data Be Submitted?	Timeframe for Submission
§158.340 Toxicology						
SUBCHRONIC TESTING (cont'd)						
82-2 - 21-Day Dermal	TGAI	A,B	No		Yes	12 Months
82-3 - 90-Day Dermal	TGAI	A,B	No		No[3/]	
82-4 - 90-Day Inhalation - Rat	TGAI	A,B	No		No[4/]	
82-5 - 90-Day Neurotoxicity	TGAI	A,B	No		No[5/]	
CHRONIC TESTING						
83-1 - Chronic Toxicity						
o Rodent	TGAI	A,B	Yes	00041408	No	
o Nonrodent	TGAI	A,B	No		Yes	50 Months
83-2 - Oncogenicity Study						
o Rat	TGAI	A,B	Yes	00041408	No	
o Mouse	TGAI	A,B	Yes	00044335	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPAZINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.340 Toxicology						
CHRONIC TESTING (cont'd)						
83-3 - Teratogenicity						
o Rat	TGAI	A,B	Yes	00150242	No	
o Rabbit	TGAI	A,B	No		Yes	15 Months
83-4 - Reproduction, 2-Generation	TGAI	A,B	Yes	00041409	No	
MUTAGENICITY TESTING						
84-2 - Gene Mutation	TGAI	A,B	Yes	00163222	No	
84-2 - Chromosomal Aberration	TGAI	A,B	Yes	00150622	No	
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,B	Yes	00150623	No	
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA	A,B	No		Yes	24 Months

1/ There is no evidence, based on propazine's chemical structure, to suggest that propazine is a neurotoxic compound.
2/ Subchronic oral studies in the rodent are unnecessary since a rat chronic study is available to support permanent tolerances. A separate subchronic oral study in nonrodents is unnecessary since a chronic study is required.
3/ This study is not needed because the existing acceptable end uses should not result in repeated human skin contact for extended periods.
4/ This study is not required because the existing end uses should not result in repeated inhalation exposure.
5/ An acute neurotoxicity study is not required on propazine; therefore, this study is not required.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPAZINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.490 Wildlife and Aquatic Organisms						
Avian and Mammalian Testing						
71-1 - Acute Single-Dose Oral LD_{50}	TGAI	A,B	No		Yes	9 Months
71-2 - Avian Dietary LC_{50}						
- Upland Game Bird	TGAI	A,B	No		Yes	9 Months
- Waterfowl	TGAI	A,B	No		Yes	9 Months
71-3 - Wild Mammal Toxicity	TGAI	A	No		No[1/]	
71-4 - Avian Reproduction	TGAI	A	No		No[2/]	
71-5 - Simulated and Actual Field Testing for Birds and Mammals	TEP	A	No		No[1/]	
Aquatic Organism Testing						
72-1 - Freshwater Fish LC_{50}						
- Warmwater	TGAI	A,B	No		Yes	9 Months
- Coldwater	TGAI	A,B	Yes	00034123	No	
72-2 - Freshwater Invertebrate LC_{50}	TGAI	A,B	No		Yes	9 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPAZINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.490 Wildlife and Aquatic Organisms						
72-3 - Estuarine and Marine Organisms LC_{50}						
- Fish	TGAI	A	No		No 3/	
- Shrimp	TGAI	A	No		Yes 4/	12 Months
- Oyster	TGAI	A	No		Yes 4/	12 Months
72-4 - Fish Early Life Stage and Invertebrate Life Cycle						
- Freshwater						
o Fish	TGAI	A	No		Yes 5/	15 Months
o Invertebrate	TGAI	A	No		Yes 5/	15 Months
- Marine/Estuarine						
o Fish	TGAI	A	No		Yes 6/	15 Months
o Invertebrate	TGAI	A	No		Yes 6/	15 Months
72-5 - Fish Life Cycle	TGAI	A	No		No 7/	
72-6 - Aquatic Organisms Accumulation (Fish)	TGAI	A	No		Yes	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPAZINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.490 Wildlife and Aquatic Organisms						
Aquatic Organism Testing (con't)						
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	A	No		No 7/	

1/ Based on toxicity data and the use patterns, this study is not required.
2/ Based on use patterns, this study is not required.
3/ This study is not required due to the low estimated environmental concentration (EEC) (0.039 ppm) and the slight toxicity to freshwater fish (LC_{50} > 10 ppm).
4/ Required to support use on sorghum because of potential exposure of estuarine/marine environments through runoff and drift.
5/ Required to support registration of an end-use product when the product is expected to be transported to water from the intended use site and it is expected to be highly persistent in this environment.
6/ Required to support the sorghum use. Propazine is primarily used on sorghum in Texas and Kansas. Over 300,000 acres of sorghum are grown in coastal counties in Texas alone. In addition, propazine is expected to be highly persistent in the aquatic environment.
7/ Based on the toxicity data and the low EEC, these studies are not required.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPAZINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be 3(c)(2)(B)?	Timeframe for Submission
§158.590 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS						
141-1 - Honey Bee Acute Contact LD_{50}	TGAI	A	Yes	00036935	No	
141-2 - Honey Bee - Toxicity of Residues on Foliage	TEP	A	No		No[1/]	
141-4 - Honey Bee Subacute Feeding Study	[Reserved][2/]					
141-5 - Field Testing for Pollinators	TEP	A	No		No[1/]	
142-1 thru 142-3 - NONTARGET INSECT TESTING - AQUATIC INSECTS	[Reserved][3/]					
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	[Reserved][3/]					

1/ As data from the acute contact test indicate low toxicity, no further testing is required.
2/ Reserved pending development of test methodology.
3/ Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS OF PROPAZINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Submission
§158.120 Product Chemistry						
Product Identity and Composition						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	No	N/A	Yes[1/]	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	No	N/A	Yes[2/]	6 Months
61-3 - Discussion of Formation of Impurities	MP	All	No	N/A	Yes[3/]	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	MP	All	No	N/A	Yes[4/]	12 Months
62-2 - Certification of Ingredient Limits	MP	All	No	N/A	Yes[5/]	12 Months
62-3 - Analytical Methods to Verify Certified Limits	MP	All	No	N/A	Yes[6/]	12 Months

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS OF PROPAZINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158 - Subpart C - Product Chemistry						
Physical and Chemical Characteristics						
63-2 - Color	MP	All	No	N/A	Yes[7]	6 Months
63-3 - Physical State	MP	All	No	N/A	Yes[7]	6 Months
63-4 - Odor	MP	All	No	N/A	Yes[7]	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	MP	All	No	N/A	Yes[7]	6 Months
63-12 - pH	MP	All	No	N/A	Yes[7,8]	6 Months
63-14 - Oxidizing or Reducing Action	MP	All	No	N/A	Yes[7,9]	6 Months
63-15 - Flammability	MP	All	No	N/A	Yes[7,10]	6 Months
63-16 - Explodability	MP	All	No	N/A	Yes[7,11]	6 Months
63-17 - Storage Stability	MP	All	No	N/A	Yes[7]	15 Months
63-18 - Viscosity	MP	All	No	N/A	Yes[7,12]	6 Months
63-19 - Miscibility	MP	All	No	N/A	Yes[7,13]	6 Months
63-20 - Corrosion Characteristics	MP	All	No	N/A	Yes[7]	15 Months

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS OF PROPAZINE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.120 Product Chemistry						
Other Requirements						
64- 1 - Submittal of Samples	N/A	All	N/A	N/A	No	

1/ The chemical name and nominal concentration of each impurity for which a certified limit is required must be submitted. In addition, the chemical name, nominal concentration, Chemical Abstracts Service (CAS) Registry Number, an purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredient, the following must also be provided: the product name, trade name, and common name; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned company code numbers.

2/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

3/ A detailed discussion of all impurities that are or may be present at $\geq$ 0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted. This discussion must also address the possible formation of nitrosamines.

4/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used. All nitrosoamines must be identified and quantified in six samples of each product; two samples of each must be analyzed shortly after production, 3 months after production, and 6 months after production. A method sensitive to 1 ppm of N-nitroso contaminants must be used. An upper limit must be provided (and certified) for all nitrosoamines found. Certifications should be submitted on EPA Form 8570-4 (Rev. 2-85).

TABLE B

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS OF PROPAZINE

§158 - Subpart C - Product Chemistry

5/ Upper and lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity present at ≥ 0.1% (w/w) and each "toxicologically significant" impurity present at < 0.1% (w/w) must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. [We defer to the Toxicology Branch regarding the toxicological significance of (i) impurities associated with the active ingredient present at <0.1% (w/w) and (ii) impurities not associated with the active ingredient.] Certifications must be submitted on EPA Form 8570-4 (Rev. 2-85).

6/ Analytical methods must be provided to determine the active ingredient and each toxicologically significant impurity and intentionally added inert for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits. [RCB defers to the Toxicology Branch regarding the toxicological significance of impurities and intentionally added inerts for which certified limits are required.]

7/ Physicochemical characteristics (color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, explodability, storage stability, viscosity, miscibility, and corrosion characteristics) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

8/ Required if the test substance is dispersible with water.

9/ Required if the product contains an oxidizing or reducing agent.

10/ Required if the product contains combustible liquids.

11/ Required if the product is potentially explosive.

12/ Required if the product is a liquid.

13/ Required if the product is a liquid and is to be diluted with petroleum solvents.

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS OF PROPAZINE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.135 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral - Rat	MP	A,B,E,F,G,H	Yes	00111699	No	
81-2 - Acute Dermal	MP	A,B,E,F,G,H	Yes	00111700	No	
81-3 - Acute Inhalation -Rat	MP	A,B,E,F,G,H	Yes	00111701	No	
81-4 - Primary Eye Irritation - Rabbit	MP	A,B,E,F,G,H	Yes	00111702	No	
81-5 - Primary Dermal Irritation	MP	A,B,E,F,G,H	Yes	00111703	No	
81-6 - Dermal Sensitization	MP	A,B,E,F,G,H	No		Yes	9 Months

II. LABELING APPENDICES

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 156.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.56(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of Part 152, Subpart I. You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§156.10 Labeling Requirements for Pesticides and Devices.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the

pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ***" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust] or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.].	[No precautionary statements required.].

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or

damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Do not use or store near heat or open flame.

(i) Directions for Use--(1) General requirements--(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) Placement of directions for use. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) Exceptions to requirement for direction for use--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment requried.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978; amended at 53 FR 15952, May 4, 1988]

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. BIBLIOGRAPHY APPENDICES

BIBGUIDE-1

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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00153713 Keller, A. (1979) Degradation of Propazine (Gesamil) in Soil Under Aerobic, Aerobic/Anaerobic and Sterile/Aerobic Conditions: Project Rept. No. 23/79. Unpublished study prepared by Ciba-Geigy Ltd.,Basle. 28 p.

00163222 Puri, E. (1986) V79 Chinese Hamster Point Mutation Test (with and without Microsomal Activation): G 30 028 Techn: Test No. 850624. Unpublished study prepared by Ciba-Geigy Limited. 28 p.

40933501 Mattson, A.; Kahrs, R.; Schneller, J. (1965) Use of Microcoulometric Gas Chromatograph for Triazine Herbicides. J. Agr. Food Chem. 13(2):120-122.

IV. FORM APPENDICES

EPA Form 8580-1

OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number:_____
Registrant's Name and Address: _____
_____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated _____ concerning a requirement for submission of "generic" data on the active ingredient _____ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidential Statement of Formula (CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated _____ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are _____ and their registration number(s) is/are _____.

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative:_____
(Signature)

Dated: _____ _____
(Typed)

EPA Form 8570-3

OMB Approval No. 2070-0057
Expires 11/30/89

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No._____ Date_____

Guidance Document for_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) MRID Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
Subpart C PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

EPA Form 8580-4

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PRODUCT SPECIFIC DATA REPORT (cont'd)

EPA Reg. No._____ Date_____

Guidance Document for_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) MRID Numbers Assigned
Subpart C PRODUCT CHEMISTRY (cont'd)					
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.340 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization.				
81-7	Acute Delayed neurotoxicity, hen				

EPA Form 8580-4 (cont'd)

EPA Form 8580-6

OMB Approval No. 2070-0057
Expires 11/30/89

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE